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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,411

09/01/2006

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VO-775

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42419 7590 04/27/2010  
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EXAMINER

PIHONAK, SARAH

ART UNIT

PAPER NUMBER

1627

MAIL DATE

DELIVERY MODE

04/27/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,411	<b>Applicant(s)</b> KUZNETSOVA ET AL.	
	<b>Examiner</b> SARAH PIHONAK	<b>Art Unit</b> 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1/19/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-18, 22-24 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4, 7-16, 22-24 and 26-28 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/10/2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This application, filed on 9/1/2006, is a national stage entry of PCT/RU05/00058, filed on 2/7/2005.

### **Priority**

A claim for foreign priority has been made to 2004106722, filed on 3/1/2004. An English abstract of the Russian patent (RU 2259819) issued from the foreign priority application has been received. The priority date given to the instant application is 3/1/2004.

### **Response to Remarks**

1. In the reply filed on 1/19/2010, claim 25 was cancelled by the Applicants, and new claims 26-28 have been added. Entry of these claims is allowed, as they do not introduce new matter. Claims 17-18 were previously withdrawn due to the restriction requirement.
2. Applicant's arguments, filed 1/19/2010, with respect to the rejection of claims 2, 5, and 6 under 35 USC 112, second paragraph have been fully considered and are persuasive. The rejection under 35 USC 112, second paragraph has been withdrawn.
3. Applicant's arguments filed 1/19/2010, regarding the rejection of claims 2-4, 7-8, 22, and 24-25 have been fully considered but they are not persuasive. The Applicants have argued that Vorobyev does not anticipate the claims as amended on 1/19/2010, because Vorobyev does not disclose a phospholipid dispersion in a water-salt medium. Additionally, the Applicants have stated that Vorobyev does not disclose or suggest the use of a phospholipid dispersion as an emulsifier. The examiner respectfully disagrees. Vorobyev discloses a perfluorocarbon emulsion comprised of a mixture of

perfluorodecaline, perfluorooctylbromide, perfluoromethyl cyclohexyl piperidine, and perfluorotributyl amine, in a salt-water medium, further comprising phospholipids.

Vorobyev identifies proxanol and phospholipids as emulsifying agents, and teaches that as the perfluorocarbon compounds are not soluble in aqueous media, the emulsifiers (phospholipids) are used to coat the perfluorocarbon particles (p. 2, 2<sup>nd</sup> paragraph; p. 3, 1<sup>st</sup> full paragraph). An emulsion is defined as a mixture of two immiscible liquids, where one liquid is dispersed throughout the other in droplets (<http://medical-dictionary.thefreedictionary.com/emulsion>). Therefore, the presence of the phospholipid as an emulsifying agent results in the creation of a dispersion in the salt-water medium. As the composition disclosed by Vorobyev is a perfluorocarbon emulsion, in a salt-water medium, with phospholipids, Vorobyev anticipates the claims. Claim 25 has been cancelled by the Applicants; the rejection of this claim is considered moot. A modified rejection has been made in view of the claim amendments, which will be discussed in detail below.

4. Regarding the rejection of claims 9-13, 14, 15, 16, and 23 under 35 USC 103(a), the Applicants have restated the arguments as applied to the rejection under 35 USC 102(b). The Applicants have argued that Vorobyev does not disclose or suggest a phospholipid dispersion in a salt-water medium, and that Trevino nor Roth et. al. do not cure this deficiency. This argument has been fully considered but is not found persuasive, for the reasons discussed above. The rejection was proper, and due to the claim amendments filed on 1/19/2010, a modified version of this rejection has been made, which will be discussed below in the office action.

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5. A courtesy copy of the International Search Report has been provided by the Applicants, which discusses the relevance of reference AN (SU 797456) to the instant application. As such, this reference has been considered by the examiner for this office action, as it pertains to the information provided by the ISR. References AR and AT (sheet 1), AS and AT (sheet 2), and AR-AT (sheet 3) listed in the IDS dated 9/5/2008 are not considered by the Applicants to be relevant to the claimed invention; therefore, the Applicants have stated that no further consideration of these documents is required by the examiner.

In a telephone conversation with the Applicants attorney, Mark Swanson, on 4/13/2010, it was discussed that claims 5 and 6, which were previously rejected under 35 USC 112, second paragraph, were found to be free of the prior art. It was disclosed to the Applicant's attorney that if claim 5 was incorporated into independent claim 24, the claims would be free of the prior art. In this office action, claims 5 and 6 have been objected to, as they are both dependent upon a rejected base claim. In the response filed on 1/19/2010, Applicants have requested a rejoinder of withdrawn method claims 17 and 18 upon allowance of a product claim. Rejoinder of these claims will be considered by the examiner upon allowance of a product claim.

Modified rejections under 35 USC 102(b) and 35 USC 103(a) have been made with regards to the claim amendments filed on 1/19/2010. Accordingly, this office action is made FINAL. Claims 1, 19-21, and 25 have been cancelled by the Applicants.

6. Claims 2-16, 22-24, and 26-28 were examined.

7. Claims 2-4, 7-16, 22-24, and 26-28 are rejected.

8. Claims 5 and 6 are objected to.

### **Claim Rejections-35 USC § 102**

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 2-4, 7-8, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Vorobyev, RU 2162692 patent publication (previously of record).

11. The instant claims are drawn to a fluorocarbon emulsion comprised of perfluorocarbon compounds perfluorodecaline and perfluorooctylbromide in a ratio between 10:1 and 1:10, in a salt-water medium, with a phospholipid emulsifier dispersed in the salt-water medium, and a mixture of perfluorinated tertiary amines, such as perfluoro-N-methylcyclohexylpiperidine and perfluorotributylamine. The instant claims are also drawn to the composition comprising 2-40% by volume fluorocarbon compounds, and 1-50% of a total content of rapidly eliminated fluorocarbon compounds.

12. Vorobyev discloses a perfluorocarbon emulsion comprised of a mixture of the compounds perfluorodecaline (PFD), perfluorooctylbromide (PFOB), and perfluoromethyl cyclohexyl piperidine(PFMCP), and perfluorotributyl amine (PFTBA) (p. 6, first full paragraph, English translation). Vorobyev teaches that perfluorodecaline and perfluorooctylbromide are rapidly eliminated biologically, while perfluoromethyl cyclohexyl piperidine and perfluorotributyl amine is retained for a longer period of time in

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biological fluids and tissues (p. 2, second paragraph-p. 3, top paragraph). Vorobyev teaches a salt-water medium emulsion (p. 6, second paragraph) and that the ratio of perfluorodecaline: perfluorooctylbromide is from 1:1 to 10:10, which is within the range instantly claimed (p. 6, second paragraph). Phospholipid emulsifiers are also present (p. 12, claim 1), and it is taught that phospholipids from egg yolk and soy are known in the art (p. 3, first full paragraph). It is taught that the phospholipid component is present from 0.4-4.8 % (p. 7, top sentence). Vorobyev identifies proxanol and phospholipids as emulsifying agents, and teaches that as the perfluorocarbon compounds are not soluble in aqueous media, the emulsifiers (phospholipids) coat the perfluorocarbon particles (p. 2, 2<sup>nd</sup> paragraph; p. 3, 1<sup>st</sup> full paragraph). An emulsion is defined as a mixture of two immiscible liquids, where one liquid is dispersed throughout the other in droplets (<http://medical-dictionary.thefreedictionary.com/emulsion>). Therefore, the presence of the phospholipid as an emulsifying agent results in the creation of a dispersion in the salt-water medium. While the proxanol compound is presented in this example, it is taught that proxanol and phospholipids are equivalent stabilizers (p. 12, claim 1). Perfluorocarbons are disclosed as being present from 1-20% (p. 7, top sentence). Ratios of rapidly eliminated perfluorocarbons: slowly eliminating perfluorocarbons are taught as being present in a ratio of 2:1, or 10:1 (p. 8, Example 1, p. 9, Example 2). Therefore, in a composition comprised of 20% perfluorocarbons, in which the ratio of perfluorooctylbromide: perfluorodecaline: perfluoro-N-methylcyclohexyl piperidine is 10:2:1, the amount of rapidly eliminated compounds (perfluorooctylbromide and

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perfluorodecaline) present is at least 15% in the emulsion, which meets the limitations of claim 4. Therefore, Vorobyev anticipates the instant claims.

### **Claim Rejections-35 USC § 103**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to



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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 9-13, 15-16, 23, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vorobyev, RU 2162692 patent publication, as applied to claims 2-4, 7-8, 22, and 24, in view of Ganong, Rev. of Medical Physiology, 17<sup>th</sup> ed., p. 221-222), and further in view of Trevino et. al., US 5,733,526 patent. All references are of previous record.

5. The rejection of claims 2-4, 7-8, 22, and 24 was discussed supra.

6. The instant claims are directed to a phospholipid emulsion comprised of a mixture of perfluorocarbons such as perfluorodecalin, perfluorooctyl bromide, and perfluoro-N-methylcyclohexylpiperidine, in a salt water medium, with adjuvant oils at a quantity of 1-15% of the total content of the phospholipids. The instant claims are also drawn to a fluorocarbon dispersion in which the mean particle size of the dispersion is in the range of 0.06-0.2  $\mu\text{m}$ , and the emulsion has an osmotic pressure in the range of 100-300 mOsmol/L. The claims are also drawn to the perfluorocarbon emulsion, in which the emulsion has a mean particle size between 0.06-0.2  $\mu\text{m}$  upon storage of at least six months in a non-frozen state at a temperature of +4°C.

7. The teachings of Vorobyev as applied to the instant claims are discussed supra. Additionally, Vorobyev also teaches that the average particle size of the perfluorocarbon emulsion mixture is 0.05  $\mu\text{m}$  (p. 10, Example 3, first full paragraph; p. 11, last paragraph, Example 5-p. 12, top two sentences). While Vorobyev does not explicitly teach that the average particle size of the perfluorocarbon emulsion is from 0.06-0.2

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$\mu\text{m}$ , the average particle size of  $0.05 \mu\text{m}$  is very close to this range, especially to the particle size of  $0.06 \mu\text{m}$ . It would have been considered routine and obvious for one of ordinary skill in the art to optimize particle size ranges based upon the teachings of the prior art. As Vorobyev teaches an average particle size which is very close to the size range instantly claimed, it would have been obvious for one of ordinary skill in the art to optimize the particle size range to  $0.06\text{-}0.2 \mu\text{m}$ , as instantly claimed. Vorobyev does not explicitly teach that the osmotic pressure of the perfluorocarbon emulsion is in the range between  $100\text{-}350 \text{ mosmol/L}$ . However, it is known in the art that the osmolality of blood plasma is usually near  $285 \text{ mosmol/L}$ , as taught by Ganong (p. 222, right column, first full paragraph). The osmotic pressure of the instantly claimed perfluorocarbon emulsion is within the range of normal blood plasma osmotic pressure. Therefore, it would have been obvious for one of ordinary skill in the art to establish an osmotic pressure range between  $100\text{-}350 \text{ mosmol/L}$ , as this range is within the normal physiological range for blood plasma. Vorobyev teaches that the perfluorocarbon emulsion is stable (English translation, p. 7, full paragraph); it is not taught that the emulsion needs to be frozen for storage. As it is taught that the emulsion is stable and safe to be used as a blood replacement and for other medical purposes (ultrasound, radiographic, and magnetic resonance), and that the average particle size is  $0.05 \mu\text{m}$ , it would have been obvious that the emulsion would have maintained a mean particle size in the range of  $0.06\text{-}0.2 \mu\text{m}$  after six months storage in a non-frozen state at a temperature of  $+ 4^{\circ}\text{C}$ . Vorobyev also teaches that perfluorotripropylamine and perfluorotributylamine are both equivalent perfluorocarbons, which are commonly used in perfluorocarbon emulsions in the

medical industry (English translation, p. 2, both paragraphs); therefore, it would have been prima facie obvious to include perfluorotripropyl amine and equivalent coproducts in the emulsion, as it is taught to be used for the same purpose as perfluorotributylamine.

Vorobyev does not explicitly teach that the perfluorocarbon emulsion further comprises adjuvant vegetable oils.

Trevino et. al. teaches a perfluorocarbon emulsion which also comprises at least one hydrocarbon oil, as well as dispersing agents (Abstract; column 4, lines 21-26). Trevino et. al. teaches that the emulsion is useful for delivering a wide variety of bioactive agents to patients, such as physiological gases (Abstract; column 7, lines 10-30). Trevino et. al. teaches that the hydrocarbon oils can be selected from soybean oil, sunflower oil, and other oils (column 4, lines 43-45; lines 65-67). It is taught that the hydrocarbon oils impart advantageous pharmaceutical properties to the emulsion, including enhanced stability and bioavailability (column 2, line 60-column 3, line 4; column 3, line 62-column 4, line 21). Phospholipids as emulsifiers are also taught (column 5, lines 33-36). Trevino teaches that the hydrocarbon oils comprise about 0.01-50 % of the emulsion, and the emulsifiers comprise between 0.01-20% of the emulsion (column 6, lines 4-10). Therefore, as the amount of hydrocarbon oil present can be 1%, and the amount of phospholipid (as emulsifier) present can be 10% of the emulsion; the adjuvant hydrocarbon oil is in a quantity between 1-15% of the phospholipid, which meets the limitation of claim 9. The addition of sugars as osmotic agents is also taught (column 15, lines 56-62). Trevino et. al. also teaches that *at least one* hydrocarbon oil is

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present in the emulsion (column 4, lines 22-26), and lists a variety of different oils, such as soybean and sunflower oil, as well as other natural oils (column 4, lines 67-67).

While ricinus oil is not explicitly taught, it is a natural oil, and Trevino et. al. teaches that other natural oils in addition to soybean and sunflower oils can be present. Therefore, it would have been obvious to one of ordinary skill in the art that mixtures of two or three oils can be used in the emulsion, as well as ricinus oil.

Vorobyev teaches that a perfluorocarbon emulsion comprised of mixtures of perfluorodecalin, perfluorooctyl bromide, perfluoro-N-methylcyclohexylpiperidine and phospholipid emulsifiers in a salt-water medium is an improved oxygen delivery carrier. Trevino et. al. teaches that the addition of hydrocarbon oils to perfluorocarbon emulsions provides increased stability and bioavailability. One of ordinary skill in the art would have been motivated to combine the perfluorocarbon emulsion taught by Vorobyev with hydrocarbon oils, because Vorobyev teaches that the emulsion comprised of mixtures of different perfluorocarbons is effective as an oxygen delivery agent and has improved properties over previous perfluorocarbon formulations, while Trevino teaches that hydrocarbon oils enhance the stability and bioavailability of perfluorocarbon emulsions. Therefore, one of ordinary skill in the art would have expected success in preparing a formulation comprised of these agents, as they are taught as being beneficial in perfluorocarbon emulsions for use as oxygen carrier agents, and for the delivery of bioactive agents, etc. Therefore, the instant claims would have been prima facie obvious to one of ordinary skill in the art at the time of the invention, in view of the prior art.

### **Claim Rejections-35 USC § 103**

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vorobyev, RU 2162692 patent publication, as applied to claims 2-4, 7-8, 22, and 24 above, and further in view of Roth et. al., US 5,344,393 patent (of previous record).
12. The rejection of claims 2-4, 7-8, and 24 is discussed supra.
13. Claim 14 is directed to a perfluorocarbon emulsion comprised of perfluorodecalin, perfluorooctyl bromide, and perfluorinated tertiary amines in a salt-water medium, with sodium and potassium chlorides and phosphates, and mannitol in injection water.
14. Vorobyev teaches perfluorocarbon emulsions comprised of perfluorodecalin, perfluorooctyl bromide, and perfluorinated tertiary amines, in a salt-water medium, with phospholipids, and sodium and potassium chlorides, and phosphates (p. 6, paragraphs 1-2; p. 11, second full paragraph).

While Vorobyev teaches that sugars such as glucose are present in the emulsion (p. 9, first full paragraph), it is not explicitly taught that mannitol is present in the emulsion.

Roth et. al. teaches a perfluorocarbon emulsion for use as an intravenous oxygen carrier (column 4, lines 55-68). Roth et. al. teaches the perfluorocarbon emulsion as prepared in injection water, along with egg yolk phospholipids, sodium chloride and sodium phosphates (column 7, Formula I, lines 34-48). Roth et. al. also teaches the addition of mannitol to the emulsion as an osmotic agent, so that the emulsion is at physiological isotonicity (column 7, lines 14-21).

One of ordinary skill in the art would have been motivated, at the time of the invention, to formulate the perfluorocarbon emulsion taught by Vorobyev with mannitol

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as an osmotic agent, because Vorobyev teaches that the perfluorocarbon emulsion comprised of mixtures of different perfluorocarbons is effective as an oxygen delivery agent and has improved properties over previous perfluorocarbon formulations, and Roth et. al. teaches that mannitol is commonly used as an osmotic agent in perfluorocarbon emulsions formulated as intravenous oxygen carriers, to enable the formulation to be at physiological isotonicity. Therefore, success would have been expected in adding mannitol to the perfluorocarbon emulsion taught by Vorobyev, as the mannitol is known in the art as an effective osmotic agent for pharmaceutical perfluorocarbon emulsions. The instant claim would have been prima facie obvious to one of ordinary skill in the art, at the time of the invention, over Vorobyev, in view of Roth et. al.

### **Claim Objections**

13. Claims 5 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/  
Primary Examiner, Art Unit 1627

S.P.